UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,401	12/19/2005	Alex Abbas	P1998R1	2193

9157 7590 04/18/2008

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
04/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,401	ABBAS ET AL.	
	Examiner	Art Unit	
	GYAN CHANDRA	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *1-8,12,13 and 18-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11 and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/30/05, 5/11/06 and 3/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group 3, Claims 9-11 and 14-17, and the polypeptide of SEQ ID NO: 130, in the reply filed on 1/23/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Status of Application, Amendments and/or Claims

Claims 1-28 are pending.

Claims 1-8, 12-13 and 18-28 are withdrawn from further consideration as being drawn to nonelected inventions.

Claims 9-11 and 14-17 are examined to the extent they read on the elected invention (i.e., the polypeptide of SEQ ID NO: 130).

Information Disclosure Statement

The Information Disclosure Statements (IDSs) submitted on 8/30/05, 5/11/06 and 3/30/2007 have been considered. The crossed out references of 3/30/07 IDS are duplicate of references which have already been considered (see the IDS of 5/11/2006).

Specification

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains numerous embedded hyperlinks and/or other form of browser-executable code. See for example, page 23,

line 22 and page 26, line 1. Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claim 9 is objected for reciting non-elected inventions (i.e., Figures 1-129 and 131-209). The Examiner suggests that syntax of claim 9 can be improved by amending the claim to replace "shown in Figures 1-209" with "of SEQ ID NO: 130"

Claims 10 and 11 are objected for directly or indirectly depending from an objected claim (i.e., claim 9).

Claims 14, 16 and 17 are objected for reciting non-elected inventions (i.e., agonist, antagonist or antibody).

Claim 15 is objected for directly depending from an objected claim 14.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-11 and 14-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-11 and 14-17 of copending Application No. US 11/536,614. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is drawn to an isolated polypeptide having at least 80% amino acid sequence identity to an amino acid sequence of the polypeptide shown in Figures 130 (SEQ ID NO: 130), a chimeric polypeptide comprising a polypeptide according to claim 9 fused to a heterologous amino acid sequence, wherein said heterologous amino acid sequence is an epitope tag sequence or an Fc region of an immunoglobulin, a composition comprising a polypeptide of claim 9 in combination with a carrier, wherein said carrier is a pharmaceutically acceptable carrier, a composition comprising a therapeutically effective amount of the same and an article(kit) comprising a container, a label on said container and a composition comprising the same, whereas claims 9-11 and 14-17 of US 11/536,614 are broadly drawn to an isolated polypeptide shown in Figure 2 (SEQ ID NO: 2), shown in Figure 4 (SEQ ID NO: 4),....., shown in Figure 130 (SEQ ID NO: 13), a chimeric polypeptide comprising a polypeptide according to claim 9 fused to a heterologous amino acid sequence, wherein said heterologous amino acid sequence is an epitope tag sequence or an Fc region of an immunoglobulin, a composition comprising a polypeptide of claim 9 in combination with a carrier, wherein said carrier is a pharmaceutically acceptable carrier, a composition

comprising a therapeutically effective amount of the same and an article(kit) comprising a container, a label on said container and a composition comprising the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11 and 14-17 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation.

The instant claims are drawn to an isolated polypeptide having at least 80% amino acid sequence identity to an amino acid sequence of the polypeptide shown in Figures 130 (SEQ ID NO: 130), a chimeric polypeptide comprising a polypeptide according to claim 9 fused to a heterologous amino acid sequence, wherein said heterologous amino acid sequence is an epitope tag sequence or an Fc region of an

immunoglobulin, a composition comprising a polypeptide of claim 9 in combination with a carrier, wherein said carrier is a pharmaceutically acceptable carrier, a composition comprising a therapeutically effective amount of the same and an article(kit) comprising a container, a label on said container and a composition comprising the same.

The specification discloses that the present invention is based on the identification of proteins (including agoinst and antagonist antibodies) which are a result of stimulation of the immune response in mammals (pg 2, lines 2-4). However, the instant specification does not teach any significance or functional characteristics of the polypeptide (SEQ ID NO: 130). The specification also does not disclose any methods or working examples that indicate the polypeptide of the instant invention are involved in any activity. There is no biological activity, expression pattern, phenotype, disease or condition, ligand, binding partner, or any other specific feature that is disclosed as being associated with the polypeptide of SEQ ID NO: 130. Without any information as to the specific properties of the polypeptide of SEQ ID NO: 130, the mere identification of the polypeptide is not sufficient to impart any particular utility to the claimed polypeptides. Since significant further research would be required of the skilled artisan to determine how the claimed polynucleotide and polypeptide are involved in any activities, the asserted utilities are not substantial. Since the utility is not presented in mature form and significant further research is required, the utility is not substantial. The specification asserts the following as patentable utilities for the claimed polypeptide of SEQ ID NO: 130:

1) to produce a variant polypeptide (pg 52, lines 18-38);

2) to screen for peptides/ligands/small molecules which specifically bind the polypeptide (pg 66, lines 32-37 through pg 68, lines 1-9);

3) in tissue distribution (pg 95, lines 9-12);

4) to produce antibodies against the polypeptide (pg 68, lines 30-40 through pg 75, line 1);

5) as a therapeutic agent (pg 75, lines 1-37 through pg 76, lines 1-18) and

6) in diagnosis and prognosis of immune related diseases (page 80, lines12-34).

Each of these shall be addressed in turn.

1) to produce a variant polypeptide. This asserted utility is not specific or substantial. Since the same assays can be performed with any polypeptide, the asserted utility is not specific to the claimed polypeptide of SEQ ID NO: 130. Furthermore, since the specification does not disclose how the polypeptide of SEQ ID NO: 130 variants can be used, significant further research would be required of the skilled artisan to determine how to use the claimed polypeptide variants. Since the asserted utility is not present in a ready to use, real-world application, the asserted utility is not substantial.

2) to screen for peptides/ligands/small molecules which specifically bind the polypeptide. This asserted utility is not specific or substantial. Since such assays can be performed with any polypeptide, the asserted utility is not specific to the claimed

polypeptide of SEQ ID NO: 130. Additionally, the specification discloses nothing specific or substantial for the proteins or other binding partners that can be identified by this method. This would constitute further research to determine the properties of the polypeptide, which clearly is of the type of experimentation that does not meet the requirements of 35 USC § 101.

3) in tissue distribution. This asserted utility is not specific or substantial. With the exception of a few housekeeping genes, all naturally occurring polypeptides have a tissue specific pattern of expression, and thus virtually any naturally occurring polypeptide can be used in tissue typing. Thus, the asserted utility is not specific to the polypeptide of SEQ ID NO: 130.

4) to produce antibodies against the polypeptide. This asserted utility is not specific or substantial. Since antibodies can be made to any polypeptide, the asserted utility is not specific to the claimed polypeptide of SEQ ID NO: 130 antibodies. Furthermore, since the specification does not disclose how polypeptide of SEQ ID NO: 130 or antibodies that bind it can be used, significant further research would be required of the skilled artisan to determine how to use the claimed polypeptide or antibodies that bind it. Since the asserted utility is not presented in a ready to use, real-world application, the asserted utility is not substantial.

5) as a therapeutic agent. This asserted utility is not specific or substantial. The specification discloses that because the nucleic acid sequence of SEQ ID NO: 129 that encodes for the polypeptide of SEQ ID NO: 130 is isolated from immune cells, the polypeptide can be used to treat many immunological diseases (more than 100

diseases) which are listed on page 76, lines 25-40 through page 78, lines 1-39. Since the asserted utility is not presented in a ready to use, real-world application, the asserted utility is not substantial.

6) in diagnosis and prognosis of immune related diseases. This asserted utility is not specific or substantial. The specification does not disclose any such disease where the polypeptide of SEQ ID NO: 130 is produced at a low or high level and that using an antibody to detect the same could be used for prognosis or diagnosis purposes. The specification only states that an antibody against a polypeptide could be used to detect the same as diagnostics or prognostics (page 80, lines13-18). Since antibodies can be made to any polypeptide and use to detect the same, the asserted utility is not specific to the claimed polypeptide of SEQ ID NO: 130 antibodies. Because the asserted utility is not presented in a ready to use, real-world application, the asserted utility is not substantial.

Claims 9-11 and 14-17 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

However, even if the claimed invention is eventually deemed to have a credible, specific and substantial asserted utility or a well established utility, claims 9-11 and 14-17 would remain rejected under 35 U.S.C. § 112, first paragraph.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include: (1) Nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the breath of the claims, (7) the quantity of experimentation needed, (8) relative skill of those in the art.

The instant disclosure fails to meet the enablement requirement for the following reasons:

The amount of direction and guidance present and the presence or absence of working examples: The specification teaches that the term "'PRO/number polypeptide' and 'PRO/number' wherein the term 'number' is provided as an actual numerical designation as used herein encompass native sequence polypeptides and polypeptide variants (pg 20, lines 12-14). The specification on page 16 discloses that the polypeptide of SEQ ID NO: 130 is encoded by nucleic acid sequence of the SEQ ID NO: 129 or PRO6492 cDNA. The PRO6492 polypeptides described herein may be isolated from a variety of sources, such as from human tissue types or from another source, or prepared by recombinant or synthetic methods (pg 20, lines 14-16). The specification discloses that a PRO polypeptide variant is defined as an active PRO polypeptide having at least about 80% amino acid sequence identity with a full-length native sequence PRO polypeptide sequence (pg 21, lines 18-25). However, the specification does not teach any variant, fragment, or derivative of the PRO6492 polypeptide other than the full-length amino acid sequence of SEQ ID NO: 130. Additionally, the

specification as filed fails to disclose any functional assay to evaluate a well established functional activity of the instant polypeptide.

The state of the prior art and the predictability or lack thereof in the art: The problem of predicting protein and DNA structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and DNA is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the DNA and protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional

configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone (Bork, 2000, Genome Research 10:398-400; Skolnick et al., 2000, Trends in Biotech. 18(1):34-39, especially p. 36 at Box 2; Doerks et al., 1998, Trends in Genetics 14:248-250; Smith et al., 1997, Nature Biotechnology 15:1222-1223; Brenner, 1999, Trends in Genetics 15:132-133; Bork et al., 1996, Trends in Genetics 12:425-427).

The breadth of the claims and the quantity of experimentation needed*:* Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of any teaching of extracellular protein structure requirements in context to the polypeptide of SEQ ID NO: 130, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 9-11 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only sets forth a polypeptide of SEQ ID NO: 130, and therefore the written description is not commensurate in scope with "any polypeptide having at least 80% sequence identity to the polypeptide of SEQ ID NO: 130."

The instant claims are directed to an isolated polypeptide having at least 80% amino acid sequence identity to the amino acid sequence of the polypeptide shown in Figure 130 (SEQ ID NO: 130), a chimeric polypeptide comprising a polypeptide according to claim 9 fused to a heterologous amino acid sequence, wherein said heterologous amino acid sequence is an epitope tag sequence or an Fc region of an immunoglobulin, a composition comprising a polypeptide of claim 9 in combination with a carrier, wherein said carrier is a pharmaceutically acceptable carrier, a composition comprising a therapeutically effective amount of the same and an article(kit) comprising a container, a label on said container and a composition comprising the same. The claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics,

structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Additionally, the description of one polynucleotide species (SEQ ID NO: 129) and one polypeptide species (SEQ ID NO: 130) is not adequate written description of an entire genus of functionally equivalent polypeptides which incorporate all variants with at least 80% sequence identity to the polypeptide comprising the amino acid sequence of SEQ ID NO: 130.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See Vas-Cath at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a

potential method of isolating it. The polypeptide itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated polypeptide consisting of the amino acid sequence of SEQ ID NO: 130, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9-11 and 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Lal et al (US Pub. No. 2003/0143686 published on 7/31/03 which is a continuation of Application PCT/US01/30424 filed on 9/28/2001).

The instant claims are drawn to an isolated polypeptide having at least 80% amino acid sequence identity to the amino acid sequence of the polypeptide shown in Figure 130 (SEQ ID NO: 130), a chimeric polypeptide comprising a polypeptide according to claim 9 fused to a heterologous amino acid sequence, wherein said heterologous amino acid sequence is an epitope tag sequence or an Fc region of an immunoglobulin, a composition comprising a polypeptide of claim 9 in combination with a carrier, wherein said carrier is a pharmaceutically acceptable carrier, and a composition comprising a therapeutically effective amount of the same.

Lat et al teach a polypeptide of SEQ ID NO: 3 which is 424 amino acids in length wherein amino acid residues 1-424 are 100% identical to the amino acids 1-424 of the polypeptide of SEQ ID NO: 130 of the instant invention (see - attached sequence alignment). Lat et al teach making a chimeric protein containing a heterologous moiety that can be recognized by an antibody to facilitate screening of peptide library or to facilitate protein purification [0184]. Lat et al teach using a number of epitopes such as GST, 6-His, FLAG, c-myc and hemagglutinin (HA) that can be recognized by an antibody [0184]. Lal et al teach a pharmaceutical composition comprising a substantially purified protein in conjunction with a suitable pharmaceutical carrier [0197]. Lal et al teach that a suitable composition comprising the active ingredients in effective amount to achieve the intended purpose and they teach that the determination of an effective

amount is well within the capability of one of the skill in the art. Thus, the cited art of record clearly anticipates the invention as claimed.

```
RESULT 1
US-10-288-252-3
; Sequence 3, Application US/10288252
; Publication No. US20030143686A1
; GENERAL INFORMATION:
;  APPLICANT: INCYTE GENOMICS, INC.
;  APPLICANT:  LAL, Preeti G.
;  APPLICANT:  TANG, Y. Tom
;  APPLICANT:  YUE, Henry
;  APPLICANT:  BURFORD, Neil
;  APPLICANT:  GANDHI, Ameena R.
;  APPLICANT:  WARREN, Bridget A.
;  APPLICANT:  YAO, Monique G.
;  APPLICANT:  TRIBOULEY, Catherine M.
;  APPLICANT:  BAUGHN, Mariah R.
;  APPLICANT:  LEE, Ernestine A.
;  APPLICANT:  HAFALIA, April J.A.
;  APPLICANT:  LU, Yan
;  APPLICANT:  GRIFFIN, Jennifer A.
;  APPLICANT:  SANJANWALA, Madhu S.
;  APPLICANT:  DING,Li
;  TITLE OF INVENTION: TRANSFERASES
;  FILE REFERENCE: PI-0241 USA
;  CURRENT APPLICATION NUMBER: US/10/288,252
;  CURRENT FILING DATE:  2002-11-04
;  PRIOR APPLICATION NUMBER: PCT US01/30424
;  PRIOR FILING DATE: 2001-09-28
;  PRIOR APPLICATION NUMBER: US 60/252,819
;  PRIOR FILING DATE: 2000-11-21
;  PRIOR APPLICATION NUMBER: US 60/249,639
;  PRIOR FILING DATE: 2000-11-16
;  PRIOR APPLICATION NUMBER: US 60/247,931
;  PRIOR FILING DATE: 2000-11-09
;  PRIOR APPLICATION NUMBER: US 60/246,001
;  PRIOR FILING DATE: 2000-11-03
;  PRIOR APPLICATION NUMBER: US 60/244,025
;  PRIOR FILING DATE: 2000-10-27
;  PRIOR APPLICATION NUMBER: US 60/238,481
;  PRIOR FILING DATE: 2000-10-06
;  PRIOR APPLICATION NUMBER: US 60/236,523
;  PRIOR FILING DATE: 2000-09-29
;  NUMBER OF SEQ ID NOS: 40
;  SOFTWARE: PERL Program
; SEQ ID NO 3
;   LENGTH: 434
;   TYPE: PRT
;   ORGANISM: Homo sapiens
;   FEATURE:
;   NAME/KEY: misc_feature
;   OTHER INFORMATION: Incyte ID No. US20030143686A1 3090127CD1
US-10-288-252-3

  Query Match             100.0%;  Score 2257;  DB 4;  Length 434;
  Best Local Similarity   100.0%;  Pred. No. 7.3e-223;
  Matches  434;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MEGAELAGKILSTWLTLVLGFILLPSVFGVSLGISEIYMKILVKTLEWATIRIEKGTPKE 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MEGAELAGKILSTWLTLVLGFILLPSVFGVSLGISEIYMKILVKTLEWATIRIEKGTPKE 60

Qy         61 SILKNSASVGIIQRDESPMEKGLSGLRGRDFELSDVFYFSKKGLEAIVEDEVTQRFSSEE 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 SILKNSASVGIIQRDESPMEKGLSGLRGRDFELSDVFYFSKKGLEAIVEDEVTQRFSSEE 120

Qy        121 LVSWNLLTRTNVNFQYISLRLTMVWVLGVIVRYCVLLPLRVTLAFIGISLLVIGTTLVGQ 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 LVSWNLLTRTNVNFQYISLRLTMVWVLGVIVRYCVLLPLRVTLAFIGISLLVIGTTLVGQ 180

Qy        181 LPDSSLKNWLSELVHLTCCRICVRALSGTIHYHNKQYRPQKGGICVANHTSPIDVLILTT 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 LPDSSLKNWLSELVHLTCCRICVRALSGTIHYHNKQYRPQKGGICVANHTSPIDVLILTT 240

Qy        241 DGCYAMVGQVHGGLMGIIQRAMVKACPHVWFERSEMKDRHLVTKRLKEHIADKKKLPILI 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 DGCYAMVGQVHGGLMGIIQRAMVKACPHVWFERSEMKDRHLVTKRLKEHIADKKKLPILI 300

Qy        301 FPEGTCINNTSVMMFKKGSFEIGGTIHPVAIKYNPQFGDAFWNSSKYNMVSYLLRMMTSW 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 FPEGTCINNTSVMMFKKGSFEIGGTIHPVAIKYNPQFGDAFWNSSKYNMVSYLLRMMTSW 360

Qy        361 AIVCDVWYMPPMTREEGEDAVQFANRVKSAIAIQGGLTELPWDGGLKRAKVKDIFKEEQQ 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 AIVCDVWYMPPMTREEGEDAVQFANRVKSAIAIQGGLTELPWDGGLKRAKVKDIFKEEQQ 420

Qy        421 KNYSKMIVGNGSLS 434
              ||||||||||||||
Db        421 KNYSKMIVGNGSLS 434
```

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lal et al ((US Pub. No. 2003-/0143686) as applied to claims 9-11 and 14-16 above, and further in view of Gurney et al (US Pub. No. 2002/0123091).

The instant claim is further drawn to an article of manufacture (Kit) comprising a container, a label on said container and a polypeptide having at least 80% sequence identity to the polypeptide of SEQ ID NO: 130.

The teachings of Lal et al are summarized as set forth supra. Even though Lal et al teach an identical polypeptide to the instantly claimed polyeptide and a

pharmaceutical composition comprising the same, Lal et al do not teach a kit comprising a container, a label and a composition comprising a polypeptide of Claim 9.

Gurney et al do teach a container, a label affixed to said container, or a package insert included in said container referring to the use of a polypeptide ([0049] and claim 2).

Therefore, have been prima facie obvious to the person of ordinary skill in the art at the time the invention was made to manufacture a kit comprising a container, a label on said container and a composition of the polypeptide of claim 9 as taught by Gurney et al. The person of ordinary skill in the art would have been motivated do so to manufacture a kit for treating a polypeptide of SEQ ID NO: 9 associated disease as taught by Gurney et al. One would have a reasonable expectation of success in manufacturing a kit comprising a container, a label on said container and a composition comprising a polypeptide of claim 9 because Gurney et al teach making a kit ,and because making a kit is routine in the art.

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra
Art Unit 1646
17 March 2008
Fax: 571-273-2922

/Robert Landsman/
Primary Examiner, Art Unit 1647